

**Notice of Allowability**

Application No.

09/298,523

Examiner

N. M. Minnifield

Applicant(s)

BRILES ET AL.

Art Unit

1645

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 12/9/04; 03/07/05.
2. ☒ The allowed claim(s) is/are 34 and 48-56; now renumbered 1-10 respectively.
3. ☒ The drawings filed on 23 August 1999 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- \* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date 7-26-04
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date attached.
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_.

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## EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Alice Choi, 45758 on March 2, 2005 and March 7, 2005.

2. Applicants' after final amendment filed December 9, 2004 is acknowledged and has been entered. Claims 34 and 42 have been amended. Claims 28-33, 35-41 and 44-47 have been withdrawn. Claims 1-27 and 43 have been canceled. Claims 34 and 42 are now pending in the present application. All rejections have been withdrawn in view of the amendments to the claims filed December 9, 2004 and the amendments to the claims set forth below.

3. The application has been amended as follows:

Please replace paragraph [0002] with the following amended paragraph:

[0002] This application is a continuation-in-part ("CIP") of U.S. application Serial No. 08/714,741, filed September 16, 1996, now U. S. Patent No. 6,500,613 [(allowed)], which is a CIP of U.S. application Serial No. 08/529,055, filed September 15, 1995, now U. S. Patent No. 6,592,876. This application is also

based upon and claims priority from U.S. Provisional application Serial No. 60/082,728, filed April 23, 1998.

Please replace paragraph [0050] with the following amended paragraph:

[0050] [Fig. 6 shows] Figs. 6A and 6B show the reactivity of PspC antiserum with selected pneumococcal lysates run in a Western immunoblot;

Please replace paragraph [0060] with the following amended paragraph:

[0060] [Figs. 16A to 21 show] Figs. 16A to 16B show the DNA [sequences (SEQ ID NOs: 70-75) of PspCs from strains E134 (SEQ ID NO: 70), D39 (SEQ ID NO: 71), BG9163 (SEQ ID NO: 72), BG8090 (SEQ ID NO: 73), L81905 (SEQ ID NO: 74), and DBL6a (SEQ ID NO: 75), respectively] sequence of PspC from strain E134 (SEQ ID NO: 70). Figs. 17A to 17B show the DNA sequence of PspC from strain D39 (SEQ ID NO: 71). Figs. 18A to 18B show the DNA sequence of PspC from strain BG9163 (SEQ ID NO: 72). Fig. 19 shows the DNA sequence of PspC from strain BG8090 (SEQ ID NO: 73). Fig. 20 shows the DNA sequence of PspC from strain L81905 (SEQ ID NO: 74). Fig. 21 shows the DNA sequence of PspC from strain DBL6a (SEQ ID NO: 75).

Claims:

1-33 (canceled)

34. (currently amended) An isolated or purified polypeptide comprising PspC, wherein the polypeptide has the amino acid sequence [selected from the group consisting] of [SEQ ID NO: 5, SEQ ID NO: 6, SEQ ID NO: 7, SEQ ID NO: 8, SEQ ID NO: 9, SEQ ID NO: 11, SEQ ID NO: 12,] SEQ ID NO: 13[, SEQ ID NO: 65, SEQ ID NO: 66, and SEQ ID NO: 67].

35-47 (canceled)

48. (new) An immunogenic, immunological, or vaccine composition comprising the polypeptide of claim 34.

49. (new) A method for eliciting an immunological response in a subject against *Streptococcus pneumoniae* comprising administering to the subject the polypeptide of claim 34.

50. (new) The method of claim 49, wherein said method is preformed by administering an injection or by oral, nasal, or mucosal administration.

51. (new) A method for eliciting an anti-PspA antibody in a subject comprising administering to the subject the polypeptide of claim 34.

52. (new) The method of claim 51, wherein said method is preformed by administering an injection or by oral, nasal, or mucosal administration.

53. (new) A method for eliciting an immunological response in a subject against *Streptococcus pneumoniae* comprising administering to the subject the composition of claim 48.

54. (new) The method of claim 53, wherein said method is preformed by administering an injection or by oral, nasal, or mucosal administration.

55. (new) A method for eliciting an anti-PspA antibody in a subject comprising administering to the subject the composition of claim 48.

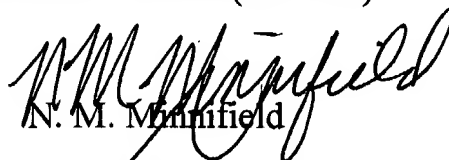
56. (new) The method of claim 55, wherein said method is preformed by administering an injection or by oral, nasal, or mucosal administration.

4. Claims 34 and 48-56 are and have been renumbered 1-10 respectively.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 571-272-0860. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R.F. Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'N. M. Minnifield', written over the printed name.

N. M. Minnifield

Primary Examiner

Art Unit 1645

NMM

March 7, 2005

***CLEAN COPY OF CLAIMS***

34. An isolated or purified polypeptide comprising PspC, wherein the polypeptide has the amino acid sequence of SEQ ID NO: 13.
48. An immunogenic, immunological, or vaccine composition comprising the polypeptide of claim 34.
49. A method for eliciting an immunological response in a subject against *Streptococcus pneumoniae* comprising administering to the subject the polypeptide of claim 34.
50. The method of claim 49, wherein said method is preformed by administering an injection or by oral, nasal, or mucosal administration.
51. A method for eliciting an anti-PspA antibody in a subject comprising administering to the subject the polypeptide of claim 34.
52. The method of claim 51, wherein said method is preformed by administering an injection or by oral, nasal, or mucosal administration.
53. A method for eliciting an immunological response in a subject against *Streptococcus pneumoniae* comprising administering to the subject the composition of claim 48.

54. The method of claim 53, wherein said method is preformed by administering an injection or by oral, nasal, or mucosal administration.

55. A method for eliciting an anti-PspA antibody in a subject comprising administering to the subject the composition of claim 48.

56. The method of claim 55, wherein said method is preformed by administering an injection or by oral, nasal, or mucosal administration.



***CLEAN COPY OF SPECIFICATION AMENDMENTS***

**[0002]** This application is a continuation-in-part ("CIP") of U.S. application Serial No. 08/714,741, filed September 16, 1996, now U. S. Patent No. 6,500,613, which is a CIP of U.S. application Serial No. 08/529,055, filed September 15, 1995, now U. S. Patent No. 6,592,876. This application is also based upon and claims priority from U.S. Provisional application Serial No. 60/082,728, filed April 23, 1998.

**[0050]** Figs. 6A and 6B show the reactivity of PspC antiserum with selected pneumococcal lysates run in a Western immunoblot;

**[0060]** Figs. 16A to 16B show the sequence of PspC from strain E134 (SEQ ID NO: 70). Figs. 17A to 17B show the DNA sequence of PspC from strain D39 (SEQ ID NO: 71). Figs. 18A to 18B show the DNA sequence of PspC from strain BG9163 (SEQ ID NO: 72). Fig. 19 shows the DNA sequence of PspC from strain BG8090 (SEQ ID NO: 73). Fig. 20 shows the DNA sequence of PspC from strain L81905 (SEQ ID NO: 74). Fig. 21 shows the DNA sequence of PspC from strain DBL6a (SEQ ID NO: 75).